UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS OF ALAN GARELY, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (hereinafter "Ethicon") submit this reply memorandum of law in further support of their motion to exclude certain opinions of Alan Garely, M.D.

LEGAL ARGUMENT

I. The Court should exclude Dr. Garely's opinions about Ethicon's knowledge, state of mind, and alleged bad acts.

Dr. Garely's report is replete with statements by Dr. Garely characterizing information found in Ethicon documents and arguing Plaintiffs' cause. Examples of several of such statements are included in Defendants' moving brief. [Doc. 2129, Def. Mov. Br. at 3]. These statements concern mere "lay matters which a jury is capable of understanding and deciding without the expert's help." *Andrews v. Metro N. Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

Federal Rule of Evidence 702 ("Rule 702") provides that a "witness who is qualified as an expert . . . may testify in the form of an opinion . . . if . . . the expert's scientific, technical, or

other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue." However, Dr. Garely's characterizations of information from company documents are not helpful to the jury. Rather, such characterizing by Dr. Garely constitutes an attempt to argue Plaintiffs' cause rather than provide specialized knowledge or expertise that would be helpful in resolving issues of fact. *See In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004).

Plaintiffs' argument that such statements constitute "Dr. Garely's citations to and summaries of the specific facts and evidence which Dr. Garely reviewed and which form part of the basis for his opinions" is disingenuous. [Doc. 2202, Pl. Opp. Br. at 6-7]. Rather, such statements, including the examples cited in Defendants moving brief, amount to advocacy on behalf of Plaintiffs which does not transform into "specialized knowledge" merely by being verbalized by Dr. Garely.

II. The Court should exclude Dr. Garely's opinions related to product warnings, as he is not qualified to testify about Prolift and Prolift+M warnings, and he has not set forth reliable and trustworthy bases for his opinions.

As Defendants have argued in the moving brief, Dr. Garely is not qualified to offer opinions with regard to the adequacy of the Prolift and Prolift+M Instructions for Use (IFUs). Plaintiffs attempt to bolster Dr. Garely's qualifications in this area by arguing that "Dr. Garely has not only used pelvic mesh products, he has proctored for and consulted with several mesh device manufacturers, including these Defendants, specifically with respect to their pelvic repair mesh products." [Doc. 2202, Pl. Opp. Br. at 9]. However, Dr. Garely's sole experience with developing an IFU occurred twenty years ago and pertained to a different category of product, an incontinence treatment device; he has no experience developing prolapse treatment labeling. (Ex. A, Alan Garely, M.D., Dep. Tr., April 15, 2016 ("Garely Tr.") at 37:5-42:4). Further, Dr.

Garely has not reviewed, to his recollection, the FDA regulations relating to labeling and instructions for use, the FDA Blue Book Memo on what is required in an IFU, or Ethicon's standard operating procedures regarding what is required of IFUs. (*Id.* at 40:5-42:4). Moreover, Dr. Garely has never used Prolift or Prolift +M, (*Id.* at 80:16-21), having categorically rejected prolapse treatment kits before either product was introduced to the market. [Doc. 2128, Def. Motion to Exclude, Ex. B, Garely General Report at 5-6]. Therefore, Dr. Garely lacks the qualifications for opining as to the adequacy of the Prolift and Prolift+M IFUs. Fed. R. Evid. 702; *see, e.g.*, *Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170, 172, 2002 WL 27284 (4th Cir. 2002).

Further, Dr. Garely has set forth numerous statements regarding Ethicon's dissemination of adverse event information that are outright false or that are entirely unsupported, as argued in Defendants' moving brief. [Doc. 2129, Def. Mov. Br. at 10-11]. Although Plaintiffs attempt to dismiss the importance of such misrepresentations by suggesting "that may present a subject for cross-examination at trial," Rule 702 provides that a witness who is qualified as an expert may testify in the form of an opinion if the testimony is "*based on sufficient facts or data.*" (Emphasis added.) Misrepresentations cannot be a sufficient basis for an expert's opinion. Dr. Garely's opinions as to product warnings should be excluded.

III. The Court should exclude Dr. Garely's opinions that amount to a mere historical commentary.

In opposing Defendants' argument that the Court should exclude Dr. Garely's opinions that amount to mere historical commentary, Plaintiffs submit that "Defendants cannot file a *Daubert* motion to prevent the jury from learning the facts that form the support for and basis of Dr. Garely's opinions." [Doc. 2202, Pl. Opp. Br. at 14]. However, Defendants seek to do no such thing. Instead, Defendants seek to preclude Dr. Garely from venturing beyond the purview

of proper expert opinion, as he repeatedly does in his report. As argued above and in Defendants' moving brief, such statements by Dr. Garely amount to mere advocacy on behalf of Plaintiffs; assertions as to Defendants' state of mind; or, at best, regurgitation of factual information, none of which is proper testimony by an expert witness, pursuant to Rule 702. The Court should exclude such testimony by Dr. Garely.

IV. The Court should exclude Dr. Garely's opinions related to FDA regulatory processes and requirements.

While Plaintiffs' counsel unequivocally represented at Dr. Garely's deposition that Dr. Garely will not offer an opinion as to whether Ethicon complied with FDA requirements or regulations in its sale or labeling of Prolift, (Ex. A, Garely Tr. at 156:10-157:5), here Plaintiffs nevertheless argue that Dr. Garely indeed should be permitted to offer such testimony. [Doc. 2202, Pl. Opp. Br. at 7-10]. Plaintiffs nonsensically attempt to bypass their own representation by characterizing their position as not an opinion but an "undeniable fact." [Doc. 2202, Pl. Opp. Br. at 14]. Not only is Dr. Garely not qualified to opine as to compliance with FDA regulatory processes and requirements, as argued in Defendants' moving brief, but such gamesmanship by Plaintiffs' counsel should not be countenanced by this Court.

Moreover, any characterization by Dr. Garely as to Defendants' removal of Prolift and Prolift+M from the market "in response to an FDA 522 Order" is improper. [Doc. 2202, Pl. Opp. Br. at 15]. Such an assertion amounts to testimony that is beyond Dr. Garely's expertise, as he is not an expert in FDA regulatory processes and requirements, as argued in Defendants' moving brief. [Doc. 2129, Def. Mov. Br. at 13-14]. It is also yet another example of mere advocacy on behalf of Plaintiffs; assertions as to Defendants' state of mind; and regurgitation of factual information, none of which is proper testimony by an expert witness, pursuant to Rule 702.

V. The Court should preclude Dr. Garely from rendering any opinion related to alleged degradation of mesh because he has admitted that it is not his opinion that polypropylene mesh degrades *in vivo*.

As Plaintiffs represent that Dr. Garely will not offer any opinion about mesh degradation, Defendants respectfully submit that this Court should grant Defendants' request as unopposed.

VI. The Court should preclude Dr. Garely from rendering an opinion on biomaterial properties of mesh, alleged nerve entrapment, alleged degradation or the design of medical devices.

Any opinion of Dr. Garely as to biomaterial or biomechanical qualities or processes should be precluded. While Dr. Garely may be qualified to state the complications he has clinically observed, he is not qualified to leap to biomaterial explanations for those complications, including polypropylene degradation, entrapment of tiny nerves in mesh pores, chronic foreign body reaction, adequate pore size, adequate weight of polypropylene, and biocompatibility of polypropylene. Dr. Garely attempts to make such a leap when he states, for example, that the mesh in Prolift or Prolift +M degrades in the human body or results in a "biomechanical mismatch between the implant and the pelvic tissues." [Doc. 2128, Def. Motion to Exclude, Ex. B, Garely General Report at 9]. He also attempts this leap when he makes assertions as to the entrapment in mesh of "tiny nerves." [*Id.* at 11]; (Ex. A, Garely Tr. at 182:16-183:20).

As Dr. Garely himself concedes, he is not a biomaterials expert. (Ex. A, Garely Tr. at 36:5-12). He has never performed any microscopic analysis of Prolift or Prolift +M or performed any animal or benchtop testing of any component of either product. (*Id.* at 86:2-87:3).

Plaintiffs argue that the Court has ruled that "familiarity with peer-reviewed, published literature, and experience in treating mesh complications, provides a sufficient basis upon which to offer an opinion regarding the in vivo behavior of mesh." [Doc. 2202, Pl. Opp. Br. at 16].

However, even if Defendants were to accept Plaintiffs' argument at face value, Dr. Garely fails to meet these qualifications. Dr. Garely does not cite peer-reviewed medical literature in support of his opinions as to biomechanical processes and qualities, and at his deposition he was unable to do so when asked. (Ex. A, Garely Tr. at 179:11-187:14; 197:1-198:4). Moreover, his experience in removing Prolift or Prolift+M meshes from patients is unreliably small—10 to 20 explants by his own estimation—none of which he examined under a microscope or performed a pathological analysis of. (Ex. A, Garely Tr. at 141:11-144:9).

Dr. Garely lacks the scientific, technical or other specialized knowledge; sufficient facts or data; reliable principles and methods; and application of any such principles and methods that would permit him to opine as to biomechanics of the mesh in Prolift and Prolift+M, and his opinions as to the same should be precluded. Fed. R. Evid. 702.

VII. The Court should preclude Dr. Garely from rendering any opinions regarding alleged safer alternative designs that have no reliable basis.

Plaintiffs' argument as to why Dr. Garely should be permitted to opine that polyvinylidene fluoride (PVDF) is a safer feasible alternative to the mesh in Prolift or Prolift+M only serves to prove Defendants' argument: they acknowledge that Dr. Garely can point to no published literature on PVDF mesh as prolapse treatment "because there is no PVDF pelvic organ prolapse product." [Doc. 2202, Pl. Opp. Br. at 20]. Plaintiffs' speculation as to why there is none fails to convert PVDF into an actual safer feasible alternative where no such product is available or has been cleared for use. Dr. Garely's opinion as to PVDF is not based on sufficient facts or data. Fed. R. Evid. 702. Plaintiffs' opposition also ignores Dr. Garely's testimony that in his opinion *no* mesh should be placed transvaginally to treat prolapse. (Ex. A., Garely Tr. at 73:17-74:1). This, too, is fatal to Dr. Garely's alternative design argument.

Further, Plaintiffs' argument that "elimination of the armed, blind trocar implantation design" is a valid safer feasible alternative also fails. [Doc. 2128, Def. Motion to Exclude, Ex. B, Garely General Report at 29]. Dr. Garely's unsupported and unexplained "elimination" proposal is utterly abstract and incomplete, and therefore not based on sufficient facts or data. Fed. R. Evid. 702. Indeed, at his deposition, Dr. Garely agreed that "regardless of mesh arms, regardless of the use of trocars, regardless of pore size, [he doesn't] think that mesh should be implanted vaginally to treat prolapse." (Ex. A, Garely Tr. at 74:9-16). For the first time, in their opposition brief, *Plaintiffs' counsel* puts forth Y-meshes and sheet meshes as safer alternative designs, [Doc. 2202, Pl. Op. Br. at 21]; this "opinion" should be excluded on this basis alone. *See Trevino v. Boston Sci. Corp.*, 2:12-cv-01617, 2016 WL 1718836 at *10 (S.D. W. Va. Apr. 28, 2016) (excluding testimony using undisclosed articles not cited in report); *accord* Fed. R. Civ. P. 26(a)(2)(B)(i). Moreover, Dr. Garely himself did not opine Y-meshes or flat meshes used in abdominal sacrocolpopexy are safer alternative designs to Prolift and Prolift+M; he has explained neither that they are safer, nor that they constitute alternative designs to Prolift and Prolift+M. Dr. Garely's opinions as to alleged safer alternative design should be excluded.

CONCLUSION

For the reasons set forth above, the Court should limit the parameters of Dr. Garely's testimony consistent with the foregoing.

Respectfully submitted,

Dated: May 31, 2016

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

/s/ Kelly S. Crawford
Kelly S. Crawford
Riker Danzig Scherer Hyland
& Perretti, LLP
Headquarters Plaza
One Speedwell Avenue
Morristown, NJ 07962-1981
(973) 451-8417
kcrawford@riker.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on May 31, 2016, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Kelly S. Crawford
Kelly S. Crawford